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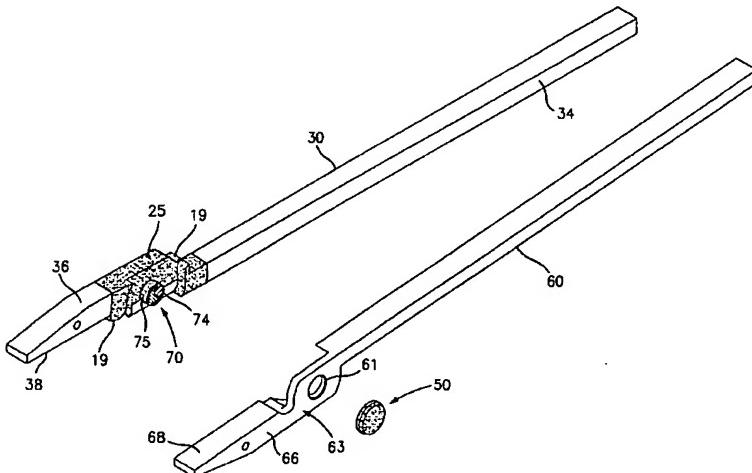
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(54) Title: MOLDED INSULATING HINGE FOR BIPOLAR INSTRUMENTS



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(57) Abstract: An electrosurgical instrument (e.g. a forceps) includes a pair of first and second elongated shafts each having an end effector attached to a distal end thereof and a handle. The handle is movable from a first position wherein the end effectors are disposed in spaced relation relative to one another to a second position wherein the end effectors are closer relative to one another. Each of the elongated shafts includes a hinge plate which mounts atop a pivot assembly for effecting movement of the end effectors relative to one another. The instrument also includes a hinge assembly made from an overmold composition which encapsulates and secures the hinge plates and the pivot assembly. The overmold composition is made from an electrically insulating material which insulates the end effectors from one another.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MOLDED INSULATING HINGE FOR BIPOLAR INSTRUMENTS**CROSS REFERENCE TO RELATED APPLICATION**

This application claims the benefits of and priority to U.S. Provisional Patent Application Serial No. 60/281,924 entitled: "MOLDED INSULATING HINGE FOR BIPOLAR INSTRUMENT" which was filed on April 6, 2001 by Sartor et al., the entire contents of this application are hereby incorporated by reference herein.

BACKGROUND**1. Technical Field**

The present disclosure relates to joints and hinges which connect movable components of an electrosurgical instrument and methods for fabricating hinges for movable components of an electrosurgical instrument. More particularly, the present disclosure relates to an easily customizable hinge made from a plastic overmold composition which connects two end effectors for relative movement therebetween. The present disclosure also relates to a method for fabricating the overmolded hinge.

2. Background of Related Art

Typically, joints and hinges for electrosurgical instruments which connect movable components are formed from an insulating material to prevent shorting between component parts and/or prevent the formation of alternate

current paths through the instrument. As such, instrument designers have manufactured electrosurgical instruments which involve complex rotating hinge configurations to isolate, insulate and/or control the electrosurgically active areas of the instrument. For example, traditional metal hinge configurations typically include multiple independent subassemblies which are overmolded with plastic material having high bond strengths. These separately overmolded subassemblies are mechanically integrated and arranged in a series of manufacturing steps that often require tightly controlled and time consuming processes to achieve proper jaw alignment and reliable and consistent gap separation between electrodes. Moreover, additional steps are often undertaken to control other parameters associated with the rotational movement about the hinge, e.g., friction, torque, etc.

Thus, a continuing need exists for a simple and effective insulating hinge that can be readily integrated into the manufacturing process to electrically isolate the movable components of an electrosurgical instrument. Further need exists for the development of a simplified manufacturing process which effectively fabricates an electrosurgical instrument which includes an insulated hinge that isolates and integrates the electrically active components of the instrument and results in the repeated formation of a reliable and easily customizable instrument which meets specific tolerance requirements for proper jaw alignment and gap distances.

SUMMARY

An electrosurgical instrument includes a pair of first and second elongated shafts each having an end effector attached to a distal end thereof and a handle. The handle is movable from a first position wherein the end effectors are disposed in spaced relation relative to one another to a second position wherein the end effectors are closer relative to one another. Each of the elongated shafts includes a hinge plate which mounts atop a pivot assembly for effecting movement of the end effectors relative to one another. The instrument also includes a hinge assembly which is overmolded to encapsulate and secure the hinge plates and the pivot assembly. The hinge assembly is made from an electrically insulating material which insulates the end effectors from one another.

Preferably, the hinge assembly is made from a composition of materials selected from the group consisting of: polyamides, nylon, arcylanitride-butane nitro styrene acetyl, polyesters, syndiotactic-polystyrene (SPS), polybutylene terephthalate (PBT), polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polyphthalamide (PPA), polymide, polyethylene perephthalate (PET), polyamide-imide (PAI), acrylic (PMMA), polystyrene (PS and HIPS), polyether sulfone (PES), aliphatic polyketone, acetal (POM) copolymer, polyurethane (PU and TPU), nylon with polyphenylene-oxide dispersion and acrylonitrile styrene acrylate. In another embodiment, the hinge assembly is made from a composition of lubricating materials selected from the group consisting of: silicon, molybdenum disulfide and light olefins.

In one embodiment, the pivot assembly includes a pivot pin integrally associated with a first of the hinge plates and a pivot hole formed within a second of the hinge plates. Preferably, the pivot pin is made from an electrically insulating material. In another embodiment, the overmold composition of the hinge assembly is disposed between the pivot pin and the pivot hole to electrically insulate each of the hinge plates from one another.

In yet another embodiment, the hinge assembly includes a retention tab which secures the hinge assembly between the hinge plates. Preferably, the retention tab is formed during the overmold process as the overmold composition leaches through the pivot pin to form a tab on the outer-facing surface of the hinge plate. Once the retention tab cures, the hinge assembly is securely held between the hinge plates. In still yet another embodiment, the hinge assembly includes a stop member for limiting the movement of the end effectors relative to one another.

The present disclosure also relates to a method of forming a hinge assembly and includes the steps of: providing a pair of first and second elongated shafts each having an end effector attached to a distal end thereof, a handle and a hinge plate. The handle is dimensioned to effect movement of the end effectors relative to one another. The method further includes the step of mounting the elongated shafts to a die block, introducing an overmold composition into the die block to encapsulate at least a portion of the hinge plates and curing the overmold composition to form the hinge assembly.

In another embodiment, the method further includes the step of: selectively positioning at least one spacer between the end effectors to maintain a gap distance between the end effectors during the molding and curing step.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed surgical instrument having a molded insulating hinge assembly are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of a bipolar forceps having a molded insulating hinge assembly constructed in accordance with the present disclosure;

FIG. 2A is an enlarged, right, side view of an end effector of the bipolar forceps of FIG. 1 prior to overmolding;

FIG. 2B is a bottom view of the end effector of FIG. 2A;

FIG. 2C is a left, side view of the end effector of FIG. 2A;

FIG. 3A is an enlarged, right, side view of a second end effector of the bipolar forceps of FIG. 1 prior to overmolding;

FIG. 3B is a bottom view of the end effector of FIG. 3A;

FIG. 3C is a left, side view of the end effector of FIG. 3A;

FIG. 4 is an exploded, perspective view of the bipolar instrument of FIG. 1; and

FIG. 5 is a perspective view of the embodiment shown in FIG. 1 shown with a spacer disposed between a pair of jaw members to fix a specific gap

distance during the overmolding process.

DETAILED DESCRIPTION

Referring now in specific detail to the drawings in which like reference numerals identify similar or identical elements throughout the several views, and initially to FIGS. 1-3C, one particular embodiment of an electrosurgical instrument 10 includes two elongated shafts 30 and 60 each having a distal end effector 32, 62 and a proximal handle portion 34 and 64, respectively. Handles 34 and 64 are movable relative to one another about a hinge assembly 20 from a first position wherein the distal end effectors 32, 62 are positioned in spaced relation relative to one another to a second position in which the distal end effectors 32, 62 cooperate to grasp tissue therebetween. It is envisioned that handles 34 and 64 may take any design configuration suitable for manipulation or control of the surgical instrument 10.

Each distal end, e.g., 32, has a jaw member 36 disposed at the distal end thereof which includes a tissue grasping surface 38 dimensioned to cooperate with the other jaw member, e.g., 66, and other tissue grasping surface, e.g., 68, to grasp tissue and other luminal structures upon actuation of the handles 34 and 64. The jaw members 36, 66 each also include a hinge plate 35, 65, respectively, which cooperate to support opposing sides of the hinge assembly 20 as explained in more detail below. Hinge plate 35 includes a pivot pin 74 which mechanically engages a corresponding pivot hole 61 disposed within hinge plate 65 to form pivot assembly 70.

Hinge assembly 20 as described herein relates to one particular embodiment for use with a bipolar electrosurgical forceps 10, however, it is contemplated that the presently disclosed hinge assembly 20 could be dimensioned for use with other electrosurgical instruments including vessel sealing instruments, grasping instruments, ablation instruments, electrosurgical scissors, etc. Moreover, it is also envisioned that the hinge assembly 20 may be configured for use with a broad range of other non-electrical surgical instruments such as pliers, scissors, shears, crimpers and wire cutters.

Preferably, hinge assembly 20 is made from a composition 25 of insulating material such as plastic which is overmolded to encapsulate the hinge plates 35, 65 during the manufacturing process. As best seen in Fig. 2C, pivot pin 74 includes a reinforcing portion 72 which allows the mold composition 25 to extrude through the pivot pin 74 of hinge plate 35 to an opposite side 63 of hinge plate 65 to form a retention tab 50. More particularly, after a significant amount of mold composition 25 is extruded around the reinforcing portion 72 of the pivot pin 74, the retention tab 50 is stamped against the opposite side 63 of hinge plate 65 to secure the hinge plates 35 and 65 in close abutment about the pivot assembly 70. As can be appreciated in this embodiment of the present disclosure, the mold composition 25 is contiguous with the exterior of the hinge plate 35 through aperture 31, around reinforcing portion 72 and with the retention tab 50 which securely engages the hinge assembly 20 between the hinge plates 35, 65.

As can be appreciated, both the mold composition 25 and the retention tab 50 are formed during the same molding step resulting in the formation of the hinge assembly 20. It is envisioned that once cured, the retention mechanism 50 forms a structural limit that at least partially controls the alignment of the distal end effectors 32 and 62 as well as the amount of pivotal movement between the jaw members 36 and 66. Alternatively, the retention tab 50 may be made from the same or a different mold composition 25 and is designed to mechanically engage the pivot pin 74 or the hinge plate 65 to secure the hinge assembly between the hinge plates 35 and 65.

As best shown in the exploded view of FIG. 4, the formation of the hinge assembly 20 in this manner electrically isolates the two end effectors 32 and 62 and the component parts thereof enabling a user to selectively apply electrosurgical energy through the tissue and between the jaw members 36 and 66 as needed. More particularly, during the overmold process, the plastic cures about the outer periphery 75 of pivot pin 74 which electrically isolates hinge plate 35 from hinge plate 65. As can be appreciated, the retention tab 50 which, as mentioned above, is also formed of plastic which extrudes through pivot pin 74 to the opposite side 63 of hinge plate 65, not only retains the two hinge plates 35 and 65 in secure abutment about the pivot assembly 70 but also electrically isolates the hinge plates 35 and 65 from one another.

Because the presently disclosed hinge assembly 20 is preferably formed during a single manufacturing step, it can be easily customized and

dimensioned to suit a particular purpose or to achieve a particular result. For example, the alignment of the jaw members 36 and 66, e.g., jaw angle or jaw offset, may be easily customized depending upon a particular purpose. Moreover, the formation of a gap distance between the jaw members 36, 66 may be easily customized. For example, the hinge assembly 20 may be molded or formed during the manufacturing process such that the jaw members 36 and 66 maintain a consistent and specific gap distance within the range of about 0.001 inches to about 0.005 inches at closure. The formation of the gap distance is discussed below with particular reference to FIG. 5.

Generally, hinge 20 is formed from an overmold composition containing a joint-forming base resin material and a lubricating component. Hinge-forming materials for use herein can be any commercially available materials known to one skilled in the art for toughness and strength as well as being capable of injection molding. Suitable joint-forming base resin materials include, but are not limited to, polyamides such as nylon, arcylanitride-butane nitro styrene; acetyl, polyesters, etc. Preferably, the overmold composition is made from a plastic or plastic-based material having a Comparative Tracking Index of about 300 volts to about 600 volts for dielectric isolation. For example, the overmold composition 25 may be made from a group of materials selected from a group which includes Nylons, Syndiotactic-polystyrene (SPS), Polybutylene Terephthalate (PBT), Polycarbonate (PC), Acrylonitrile Butadiene Styrene (ABS), Polyphthalamide (PPA), Polymide, Polyethylene Terephthalate (PET), Polyamide-imide (PAI), Acrylic (PMMA), Polystyrene (PS and HIPS), Polyether Sulfone

(PES), Aliphatic Polyketone, Acetal (POM) Copolymer, Polyurethane (PU and TPU), Nylon with Polyphenylene-oxide dispersion and Acrylonitrile Styrene Acrylate. Alternatively, it is envisioned that a non-plastic insulating material, e.g., ceramic, may be used in lieu of or in combination with one or more of the above-identified materials to facilitate the manufacturing process and possibly contribute to more uniform and consistent transfer of electrosurgical energy across the tissue.

Suitable lubricating components for use with the base resin material include a broad range of materials known to compliment the overmold composition to provide mold having a low bonding strength with good surface lubricating qualities. Such lubricating components include, but are not limited to, silicon-like materials, molybdenum disulfide, light olefins, etc.. Depending upon the overall composition of the base resin material being used, a lubricating component may not be required.

It is also anticipated that additional materials may be employed in combination with the above materials to achieve suitable levels of toughness and strength in the molded hinge 20. These additional materials may include, for example, reinforcing agents such as glass fibers, ground glass, or elongated glass fibers. For example, in one particular embodiment, hinge assembly 20 is formed from a commercially available nylon material having about 2.5 wt. % glass fiber reinforcing material and a silicone lubricating component in the range of about 0.75 wt. % to about 10 wt. %. In another embodiment, hinge assembly 20 may be

formed from a nylon having glass fiber reinforcing material in the range of about 5 wt. % to about 40 wt. % and silicone in the range of about 2 wt. % to about 8 wt. %.

While silicone or other lubricating agents are typically used in injection molding processes, it has been found that the amount of silicone should be tightly controlled to provide uniform and consistent curing and operating efficiencies. It is envisioned that the silicone component of the overmold composition creates a sustained lubricated surface at the interface between hinge plates 35 and 65. It has also been found that increasing the level of silicone, e.g., amounts greater than 2 wt. %, in the joint-forming material of hinge assembly 20, produces an overmold composition having a low bond strength. As can be appreciated, although the overmold composition 25 has a low bond strength to the surrounding metals, i.e., elongated shafts 30, 60 and hinge plates 35, 65, the low bonding strength is offset by the mechanical advantages of the retention tab 50 and aperture 31.

As mentioned above, the presently disclosed hinge assembly 20 may be formed during a single manufacturing step and may be easily customized depending upon a particular purpose or to achieve a particular result. For example, parameters such as self lubrication of the hinge assembly 20, hinge assembly 20 strength, jaw member 36, 66 alignment, e.g., jaw angle or jaw offset, isolation of the jaw members 36 and 66 during electrosurgical application and the formation of a gap distance between the jaw members 36 and 66 (or electrodes or

probes attached to the jaw members 36 and 66) may be easily achieved.

The present application is not limited to the above identified materials, but contemplates a broad range of overmold composition 25 in varying combinations and amounts that provide an overmold composition suitable for the function of hinge assembly 20. It is envisioned that applications described herein relating to the injection overmolding of thermoplastic polyamides, for example, may be translated into other areas including, but not limited to, other engineering plastic materials, engineering metals and ceramics that may be selectively applied in varying insulative as well as mechanical applications.

The overmold composition 25 of the present disclosure is configured to create a tough and strong hinge assembly 20 by at least partially encapsulating the hinge plates 35 and 65 and the pivot assembly 70 (and the various components thereof). The overmold composition 25 provides suitable strength as a result of its continuity of encapsulation as well as the ability of the overmold composition 25 to form surface features which are specifically dimensioned to improve the strength of the hinge assembly 20 once cured. For example, features within the pivot pin 74 and features within the pivot hole 61 may be provided to increase the overall strength of the instrument and/or hinge assembly 20, e.g. notches, detents, cavities, overmolded posts, etc. Further, structural strength for the hinge assembly 20 may be gained by coating or filling features defined in the surface of the hinge plates 35, 65 to augment the mechanical bonding of the plastic mold with the hinge plates 35, 65, pivot pins 74 and pivot holes 61. For

example, surface undulations such as lip structures, overhanging shapes, concave shapes, or cantilevered structures having different geometric shapes may be employed to mechanically engage the hinge assembly 20 to the hinge plates 35.

Preferably, the elongated shafts 30, 60 are made from a stainless steel material. However, other metal alloys, plastics, ceramics, or composites are also contemplated including combinations of one or more plastics, composites, metals, graphite, carbon-coated plastics and/or any other conductive materials which are well suited for overmolding purposes. Preferably, the elongated shafts 30 and 60 are die-cut, stamped, or micro-machined such that the end effectors 32 and 62 and the hinge plates 35 and 65 from integral parts thereof. As can be appreciated, making these elements integral and utilizing the overmold hinge assembly 20 as presently disclosed herein greatly simplifies the overall manufacturing and assembly processes.

Instrument 10 may also include surface treatments (e.g., nylon powder coatings, chemical treatments, nickel alloy coatings, mechanical finish treatments, shrink tubing, etc.) which facilitate manipulation of the tissue structures, enhance conduction of electrosurgical energy across the jaw members 36, 66 and/or reduce the likelihood of inconsistencies across the treatment area which may lead to collateral tissue damage, flashover, thermal spread, arcing, etc.

Preferably, the thickness of the hinge assembly 20 can be selectively altered depending upon a particular purpose or for use with a certain instrument. The ultimate thickness and strength of the overmold composition 25 is also related to the viscosity of the overmold composition 25 and the duration and temperature of the curing process. For example, the hinge assembly 20 may include a range of thickness from about 0.020 to about 0.040 inches in thickness. The thickness of the overmold composition 25 also depends on mechanical load bearing and dimensional requirements of a particular application.

As best shown in FIG. 4, the outer periphery 75 of pivot pin 74 provides a basis for the formation of additional molded material around the pivot pin 74 which not only electrically insulates the jaw members 36 and 66 from one another but also reduces the chances of the pivot slipping or rotating when torquing, cross-loading, or shearing forces are applied during the normal use of instrument 10.

It is envisioned that the hinge assembly may be designed as a more complex mechanism and/or may be designed to encapsulate a more complex pivoting mechanism. For example, it is contemplated that the hinge assembly 20 may include various multiple-link systems such as a two-bar, three-bar or four-bar linkage or may include a two-step hinge. The pivot pin 74 and/or the pivot hole 61 may also be dimensioned in a variety of different shapes and sizes depending upon a particular purpose or to achieve a particular result, e.g., cam and cam-follower, arcuate, elliptical, etc. It is also envisioned that the hinge assembly 20

may include one or more stop members 19 which limit the overall distance that the jaw members 36, 66 may pivot in either the open or closed positions. The stops 19 may be configured in steps or as a cantilevered feature to define more than one gap distance between jaw members 36 and 66.

In one embodiment, retention tab 50 may be configured to mechanically engage a portion of the hinge plate 65 and/or pivot pin 74 which is contemplated to serve two purposes: 1) to mechanically retain the retention tab 50 against the hinge plate 65 and further secure the instrument 10 as assembled; and 2) to bias the pivot assembly 70 to a predetermined open, closed, or intermediary position. For example, the outer-facing surface 63 of hinge plate 65 may be provided with slots or grooves (not shown) which mechanically engage the retention tab 50.

With respect to the particular surgical instrument of FIGS. 1-4, i.e., bipolar forceps 10, first and second conductive wires 41 and 45 are each electrically coupled to a respective distal end effector 32 and 62 at one end thereof and ultimately connected to an electrosurgical generator (not shown) at the opposite end thereof. The first electrical conductor 41 (see FIG. 2A) connects the first jaw member 36 to a first electrical potential and the second electrical conductor 45 (see FIG. 3A) connects the second jaw member 66 to a second electrical potential. Preferably, the first and second electrical conductors 41 and 45 are disposed within longitudinally-oriented channels defined within elongated shafts 30 and 60, respectively. The channels are preferably oriented and

dimensioned to facilitate mechanical engagement of the electrical conductors 41 and 45 with the respective jaw members 36 and 66 in such a manner to allow free, pivotable movement of the jaw members 36 and 66 relative to one another. Preferably, the cable leads are attached to the electrically conductive jaw members 36 and 66 by a crimp-like electrical connection (not shown). As mentioned above, the hinge assembly 20 includes at least one stop 19 which abuts against elongated shafts 30, 60 to prevent over-rotation of the jaw members 36 and 66 to avoid straining the electrical leads.

Preferably, hinge assembly 20 is manufactured in a single injection molding or manufacturing process step in which elongated shafts 30 and 60 are mounted atop a die block within an injection molding machine. The overmold composition 25 of the hinge assembly 20 is then injected between the jaw members 36 and 66 to encapsulate the hinge plates 35 and 65 and the pivot assembly 70. As mentioned above, the hinge assembly 20 is strengthened by the continuity of the plastic overmold composition 25 which extrudes through the pivot pin 74 and pivot hole 61 to form the retention tab 50. Thus, in one particular embodiment, the hinge assembly 20 is completely formed by overmold composition flowing around and through the various components parts of the hinge assembly 20 and the pivot assembly 70. As mentioned above, the retention tab may be a separate component made from the same or a similar composition which is dimensioned to mechanically engage the pivot pin 74 or the outer-facing surface 63 of the hinge plate 65.

As mentioned briefly above and as shown in FIG. 5, a spacer 100 may be positioned between jaw members 36 and 66 prior to the overmolding process. The spacer 100 sets a fixed gap distance "G" between jaw members 36 and 66 at closure (i.e., when the jaw members 36 and 66 are disposed in the closed or tissue grasping position) by limiting the formation of the stop 19 during the overmolding process. As can be appreciated, different and/or customized gap distances "G" between the jaw members 36 and 66 can be easily formed depending upon a particular purpose or to achieve a particular result.

The presently disclosed overmolding process also enables the manufacturer to customize the precise alignment of the jaw members 36 and 66 relative to one another. Thus, in applications in which the alignment of jaw members 36 and 66 is critical, such as for shearing, cutting and sealing, the accuracy, alignment and configuration of the hinge assembly 20, pivot assembly 70 and jaw members 36 and 66 can be easily customized. Further, the presently disclosed process also provides a repeatable and reliable alignment tool for mass manufacturing of surgical instruments according to specific tolerances.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the present disclosure. For example, it is contemplated that hinge assembly 20 can be configured to join a plurality of different components or subassemblies in the assembly depending upon a particular purpose. Moreover, the outer periphery 75

of pivot pin 74 could also include features such as a series of undulations or knurling, or a series of radially aligned cavities having features within those cavities that strengthen the mechanical interface of the overmold composition to the pivoting assembly 70.

In one embodiment, the instrument includes a conductive strip (not shown) disposed through one shaft, e.g., shaft 30. Electrosurgical wires or cables (not shown) from an electrosurgical generator (not shown) connect the two electrical potentials to the conductive strip. The opposite end of the conductive strip includes one electrical connection to end effector 32 and a second electrical connection to pivot assembly 70 which provides electrical continuity to the opposite end effector 62. More particularly, the second electrical connection of the conductive strip makes contact across the moving junction of the pivot assembly. It is not necessary that the conductive strip wrap around the pivot pin 74 between the instrument halves because during the molding process the conductive strip is forced into intimate contact with the opposite end effector 62, i.e, the flow of the uncured hinge material positions the conductive strip into contact with end effector 62.

As a result thereof, secondary washers or force loading devices are not required to initiate contact between the conductive strip and the opposite end effector 62. The conductive strip may also include a series of wave-like folds, e.g., accordion folds, which give the conductive strip a spring-like quality and which fosters contact with the opposite end effector 62 during and after curing. As can

be appreciated, this arrangement assures that a moving or sliding contact is maintained between the conductive strip and the end effector 62 during movement, i.e., pivoting, of the end effectors relative to one another.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. An electrosurgical instrument comprising:

a pair of first and second elongated shafts each having an end effector attached to a distal end thereof and a handle, said handle being movable from a first position wherein the end effectors are disposed in spaced relation relative to one another to a second position wherein the end effectors are closer relative to one another;

each of said elongated shafts including a hinge plate which mounts atop a pivot assembly for effecting movement of the end effectors relative to one another; and

a hinge assembly which is made from an overmold composition which, when cured, encapsulates said hinge plates, said overmold composition of said hinge assembly being made from an electrically insulating material which insulates each of said end effectors from one another.

2. An electrosurgical instrument according to claim 1 wherein said pivot assembly includes a pivot pin integrally associated with a first of said hinge plates and a pivot hole formed within a second of said hinge plates, said pivot pin being made from an electrically insulating material.

3. An electrosurgical instrument according to claim 1 wherein said pivot assembly includes a pivot pin integrally associated with a first of said hinge plates and a pivot hole formed within a second of said hinge plates, said

overmold composition of said hinge assembly when cured being disposed between said pivot pin and said pivot hole to electrically insulate each of said hinge plates from one another.

4. An electrosurgical instrument according to claim 1 wherein said overmold composition of said hinge assembly includes materials selected from the group consisting of: polyamides, nylon, arcylanitride-butane nitro styrene, acetyl, polyesters, syndiotactic-polystyrene (SPS), polybutylene terephthalate (PBT), polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polyphthalamide (PPA), polyimide, polyethylene perephthalate (PET), polyamide-imide (PAI), acrylic (PMMA), polystyrene (PS and HIPS), polyether sulfone (PES), aliphatic polyketone, acetal (POM) copolymer, polyurethane (PU and TPU), nylon with polyphenylene-oxide dispersion and acrylonitrile styrene acrylate.

5. An electrosurgical instrument according to claim 4 wherein said overmold composition of said hinge assembly includes lubricating materials selected from the group consisting of: silicon, molybdenum disulfide and light olefins.

6. An electrosurgical instrument according to claim 1 wherein said hinge assembly includes a retention tab which secures said hinge assembly between said hinge plates.

7. An electrosurgical instrument according to claim 4 wherein said pivot assembly includes a pivot pin integrally associated with a first of said hinge plates and a pivot hole formed within a second of said hinge plates, said pivot pin including a reinforcing portion disposed therein which permits said overmold composition of said hinge assembly to extrude through said pivot pin to form a retention tab for securing said hinge assembly between said hinge plates.

8. An electrosurgical instrument according to claim 1 wherein said hinge assembly includes a stop member for limiting the movement of said end effectors relative to one another.

9. A method of forming a hinge assembly comprising the steps of:

providing a pair of first and second elongated shafts each having an end effector attached to a distal end thereof, a handle and a hinge plate, said handle for effecting movement of the end effectors relative to one another;

mounting said elongated shafts to a die block;

introducing an overmold composition into said die block to encapsulate at least a portion of said hinge plates; and

curing said overmold composition to form said hinge assembly.

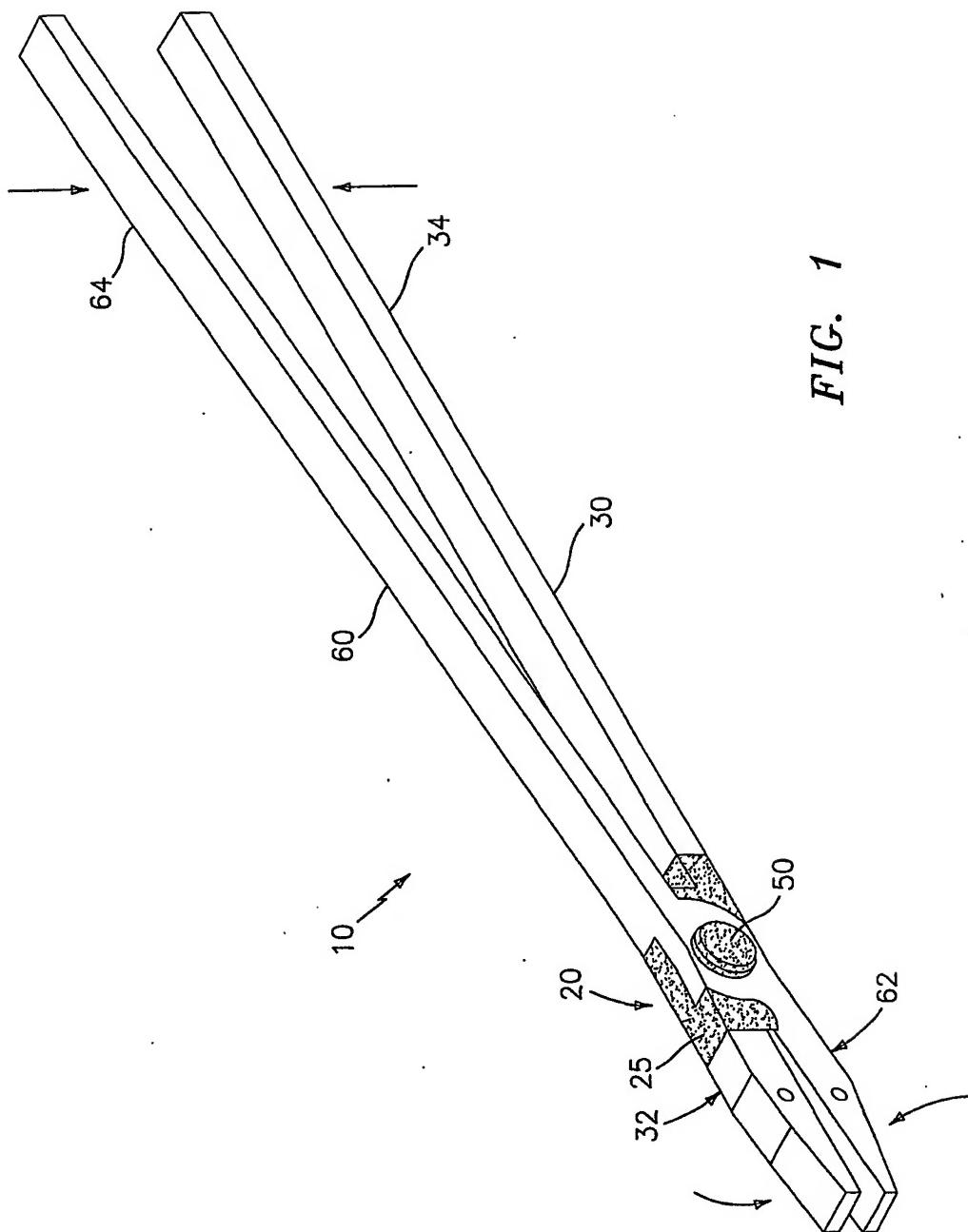
10. A method according to claim 9 wherein prior to said curing step, the method further includes the step of:

selectively positioning at least one spacer between said end effectors to maintain a gap distance between said end effectors during the curing step.

11. A method according to claim 9 wherein said overmold composition of said introducing step includes materials selected from the group consisting of: polyamides, nylon, arcylanitrile-butane nitro styrene acetyl, polyesters, syndiotactic-polystyrene (SPS), polybutylene terephthalate (PBT), polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polyphthalamide (PPA), polymide, polyethylene perephthalate (PET), polyamide-imide (PAI), acrylic (PMMA), polystyrene (PS and HIPS), polyether sulfone (PES), aliphatic polyketone, acetal (POM) copolymer, polyurethane (PU and TPU), nylon with polyphenylene-oxide dispersion and acrylonitrile styrene acrylate.

12. A method according to claim 9 wherein said overmold composition of said introducing step includes lubricating materials selected from the group consisting of: silicon, molybdenum disulfide and light olefins.

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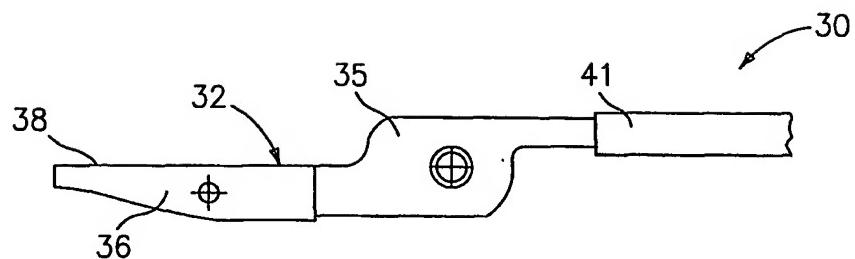


FIG. 2A

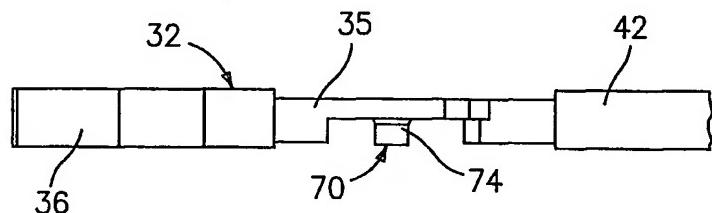


FIG. 2B

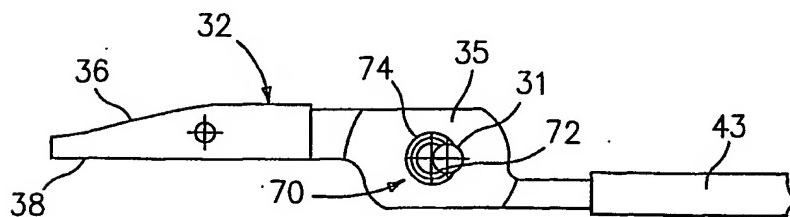


FIG. 2C

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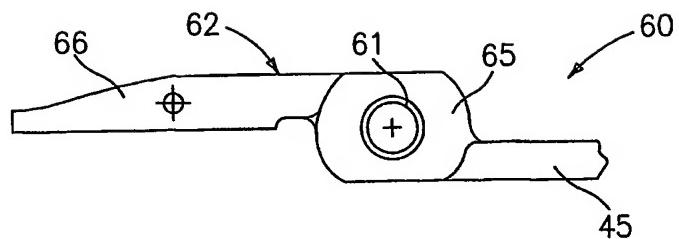


FIG. 3A

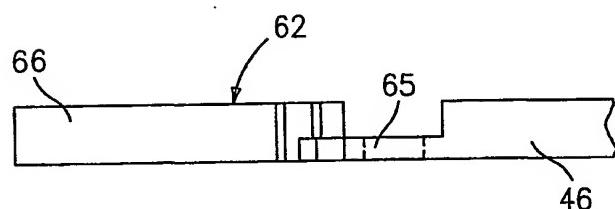


FIG. 3B

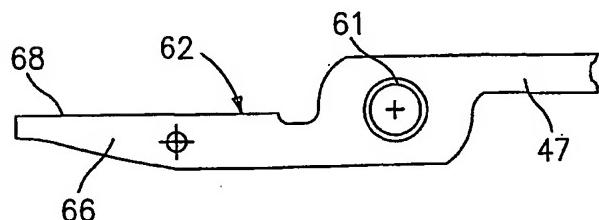
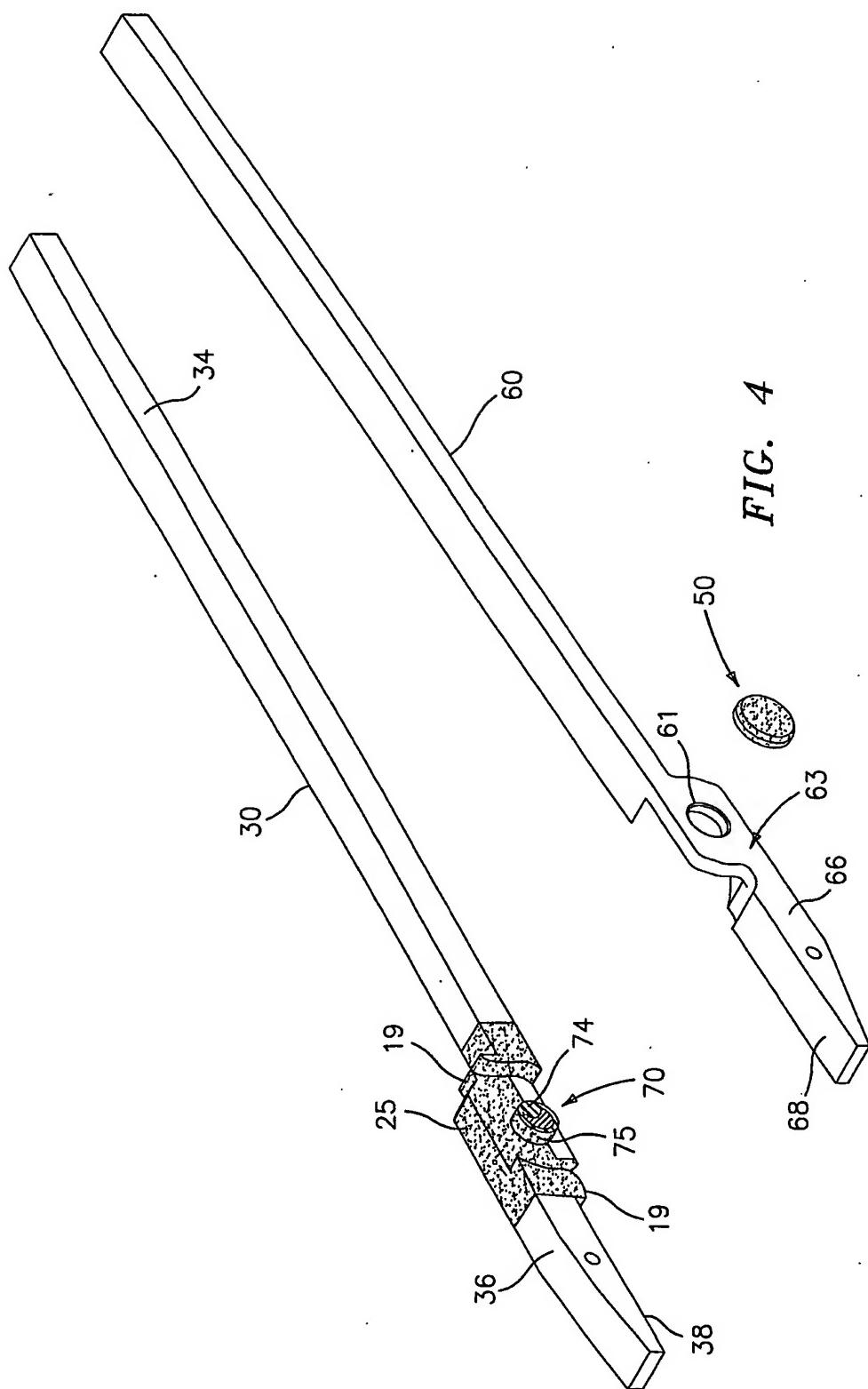


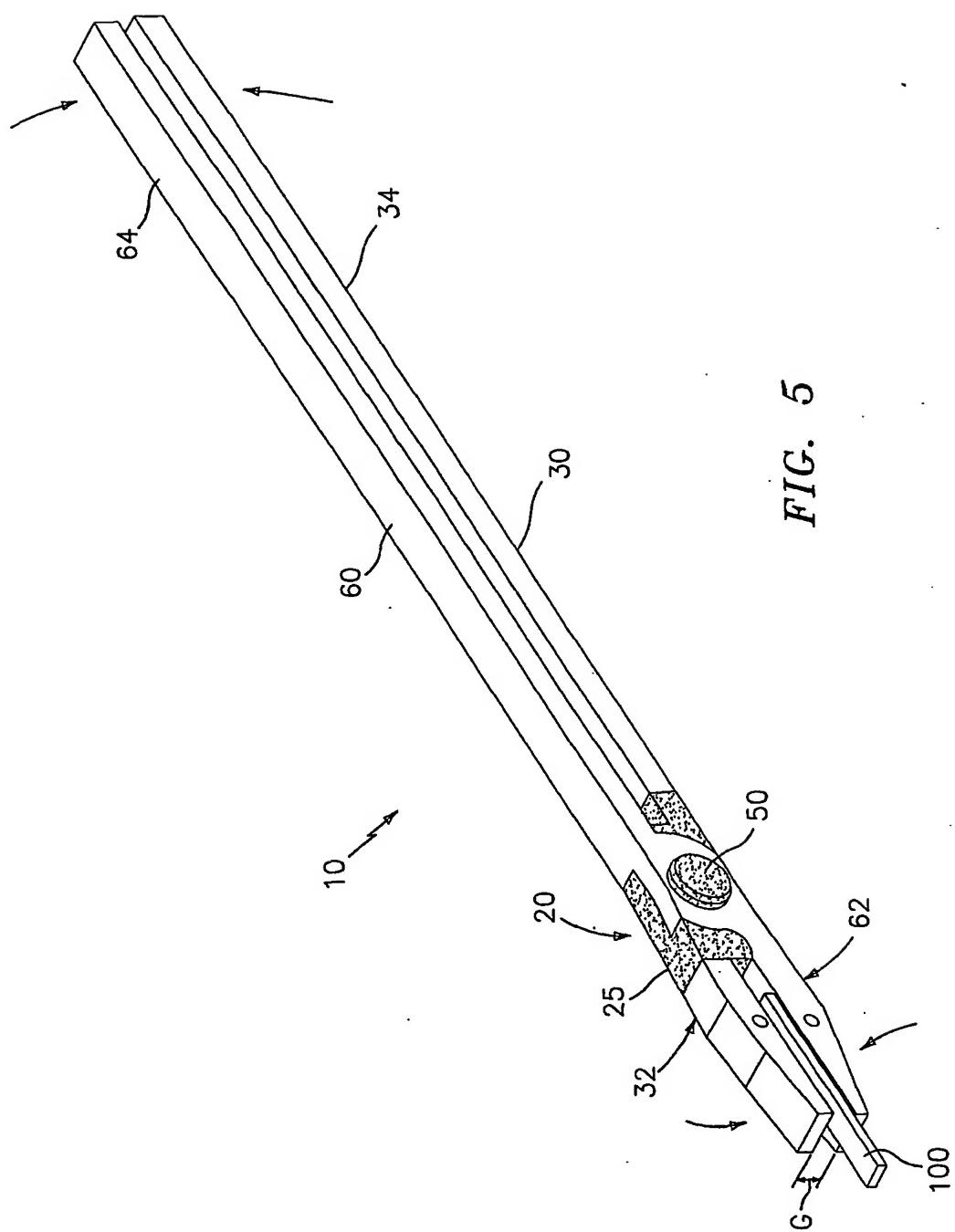
FIG. 3C

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SUBSTITUTE SHEET (RULE 26)

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INTERNATIONAL SEARCH REPORT

Inten Application No
PCT/US 02/11100

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 624 348 A (UNITED STATES SURGICAL CORP) 17 November 1994 (1994-11-17) column 8, line 28-32; figure 2 ----	1,9
A	US 6 041 679 A (KRATSCH PETER ET AL) 28 March 2000 (2000-03-28) column 5, line 24-29; figure 2 ----	1,9
A	US 6 053 914 A (WENZLER PETER ET AL) 25 April 2000 (2000-04-25) column 2, line 60 -column 3, line 8 ----	1,9
P,A	EP 1 159 926 A (AESCLAP WERKE AG) 5 December 2001 (2001-12-05) paragraph '0014! ----	1,9 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the International search

9 July 2002

Date of mailing of the International search report

16/07/2002

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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